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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,526	03/10/2004	Michael John Cuppy	22,239-06US	4531

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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT	PAPER NUMBER
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3709

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09/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/797,526

Applicant(s)

CUPPY, MICHAEL JOHN

Examiner

Shefali D. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07/29/2005.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Cuppy (US 5,755,709).

In regards to claim 23, Cuppy teaches:

- a. a hollow housing having a distal end, a proximal end, and a cavity, said proximal end connected to a catheter having an elongated catheter sheath extending in a predetermined direction (Figure 2, cylindrical body section of housing [28] and catheter tube [30]).
- b. a self-sealing injection port in fluid communication with the cavity (Figure 2, self-sealing injection port [40]; column 6, lines 21-26).
- c. a subhousing having a pair of ends including a first end connected to the housing and a second end connected to an IV line which extends generally in the predetermined direction, wherein the housing and subhousing together define a generally U-shaped structure (Figure 2, coupling/vent cap region of housing [46] and cylindrical body section of housing [28]; column 10, lines 56-57).

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- d. a unidirectional fluid valve permitting solution flow from the subhousing to the housing while substantially preventing solution flow from the housing to the subhousing (Figure 2, check valve [38]; column 6, lines 17-21 and lines 33-38).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 6-20 and 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cuppy as applied to claim 23 above, in view of Inman et al (US 4,578,063).

In regards to claims 1, Cuppy teaches:

- a. a housing having a distal end, a proximal end, and a cavity, said proximal end being adapted to connect to a catheter (Figure 2, cylindrical body section of housing [28] and catheter tube [30]).
- b. a self-sealing injection port in fluid communication with the cavity (Figure 2, self-sealing injection port [40]; column 6, lines 21-26).
- c. a subhousing having a pair of ends (Figure 2, coupling/vent cap region of housing [46]).

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- d. a unidirectional fluid valve permitting solution flow from the subhousing to the housing while substantially preventing solution flow from the housing to the subhousing (Figure 2, check valve [38]; column 6, lines 17-21 and lines 33-38).

Cuppy does not teach that the subhousing is movably connected at one end to the housing so that the position of the other end of the subhousing relative to the housing can be selectively adjusted within a range of positions. Inman et al teaches a swivel connector between an implant device and an internal body conduit to allow for proper placement of the internal body conduit with respect to the implant device and to the patient's body (column 7, lines 44-45; column 8, lines 36-42). It would have been obvious to apply the swivel joint taught by Inman et al between the subhousing and the housing of the modified device of Cuppy since the swivel joint can have various bends or angles (column 8, lines 39-42) enabling the subhousing to be moved in a direction that is more comfortable for the patient's body.

In regards to claim 11, Cuppy teaches:

- a. a catheter adapted for entry into a vascular system (column 5, line 57; Figure 1, catheter assembly [12] with catheter tube [30])
- b. a vascular access device having:
 - i. a hollow housing having a distal end, a proximal end, and a cavity, said proximal end being adapted to connect to a catheter (Figure 2, cylindrical body section of housing [28] and catheter tube [30]).
 - ii. a self-sealing injection port in fluid communication with the cavity (Figure 2, self-sealing injection port [40]; column 6, lines 21-26).

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- iii. a subhousing having a pair of ends (Figure 2, coupling/vent cap region of housing [46]).
- iv. a unidirectional fluid valve permitting solution flow from the subhousing to the housing while substantially preventing solution flow from the housing to the subhousing (Figure 2, check valve [38]; column 6, lines 17-21 and lines 33-38).

Cuppy does not teach that the subhousing is movably connected at one end to the housing so that the position of the other end of the subhousing relative to the housing can be selectively adjusted within a range of positions. Inman et al teaches a swivel connector between an implant device and an internal body conduit to allow for proper placement of the internal body conduit with respect to the implant device and to the patient's body (column 7, lines 44-45; column 8, lines 36-42). It would have been obvious to apply the swivel joint taught by Inman et al between the subhousing and the housing of the modified device of Cuppy since the swivel joint can have various bends or angles (column 8, lines 39-42) enabling the subhousing to be moved in a direction that is more comfortable for the patient's body.

In regards to claims 2 and 12, Cuppy teaches that the housing is generally linearly aligned so that the self-sealing injection port is opposite the proximal end (Figure 2, cylindrical body section of housing [28] and self-sealing injection port [40]).

In regards to claims 3 and 13, Cuppy does not teach that the subhousing is connected to the housing via a swivel joint. Inman et al teaches a swivel connector between an implant device and an internal body conduit (column 7, lines 44-45; column 8, lines 36-42). It would have been obvious to apply the swivel joint taught by Inman et al between the subhousing and the housing

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of the modified device of Cuppy since the swivel joint can have various bends or angles (column 8, lines 39-42) that allow the subhousing to be moved in a direction that is more comfortable for the patient's body.

In regards to claims 6 and 14, Cuppy does not teach a second self-sealing injection port that is connected to the subhousing, but Cuppy does teach one self-sealing injection port in fluid communication with the cavity of the housing (Figure 2, self-sealing injection port [40]; column 6, lines 21-26). To a person having ordinary skill in the art, the purpose of the self-sealing injection port is to permit the patient to be medicated (column 4, lines 16-18) while maintaining sterile conditions between the device and the patient. Cuppy teaches that at the free end of the subhousing, an IV line can be connected (column 6, lines 37-38) and that a second IV line can be connected to the self-sealing injection port of the housing for medicament administration (column 4, lines 27-30). It would have been obvious to apply the self-sealing injection port of the housing taught by Cuppy to the subhousing of Cuppy in order to provide a self-seal between the IV line and the subhousing and to maintain sterile conditions between the device and the patient at the subhousing site.

In regards to claims 7 and 15, Cuppy teaches that the pair of ends of the subhousing are separated by approximately 90 degrees (Figure 2, coupling/vent cap region of housing [46]).

In regards to claim 8, Cuppy teaches a cap for sealing one of the pair of ends of the subhousing (Figure 2, vent cap [24] and coupling/vent cap region of housing [46]; column 6, lines 12-15).

In regards to claims 9 and 16, Cuppy teaches that the fluid valve is carried within the housing (column 6, lines 18-19; Figure 2, check valve [38]).

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In regards to claims 10 and 17, Cuppy teaches that the fluid valve includes a movable disk-shaped element (Figure 2, check valve [38]).

In regards to claim 18, Cuppy teaches a needle received within the catheter (Figure 8, needle [18] and catheter tube [30]).

In regards to claim 19, Cuppy teaches:

- a. providing a vascular access device having
 - i. a hollow housing having a distal end, a proximal end, and a cavity (Figure 2, cylindrical body section of housing [28])
 - ii. a self-sealing injection port in fluid communication with the cavity (Figure 2, self-sealing injection port [40]; column 6, lines 21-26)
 - iii. a subhousing having a pair of ends (Figure 2, coupling/vent cap region of housing [46]).
 - v. a unidirectional fluid valve (Figure 2, check valve [38]; column 6, lines 17-21 and lines 33-38).
- b. connecting the vascular access device to a catheter at its proximal end (column 15, lines 30-31; Figure 2, cylindrical body section of housing [28] and catheter tube [30]).
- c. connecting the vascular access device to a fluid line at one end of the subhousing (column 6, lines 36-38).
- d. flowing fluid from the subhousing to the housing and through the fluid valve (column 6, lines 17-21 and lines 33-38).

Cuppy does not teach that the subhousing is movably connected at one end to the housing so that the position of the other end of the subhousing relative to the housing can be selectively adjusted

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within a range of positions. Inman et al teaches a swivel connector between an implant device and an internal body conduit to allow for proper placement of the internal body conduit with respect to the implant device and to the patient's body (column 7, lines 44-45; column 8, lines 36-42). It would have been obvious to apply the swivel joint taught by Inman et al between the subhousing and the housing of the modified device of Cuppy since the swivel joint can have various bends or angles (column 8, lines 39-42) enabling the subhousing to be moved in a direction that is more comfortable for the patient's body.

In regards to claim 20, Cuppy teaches withdrawing fluid within the housing through the self-sealing injection port (column 15, lines 37-39; column 16, lines 38-39).

In regards to claim 24, Cuppy does not teach that the subhousing is movably connected to the housing via a swivel joint. Inman et al teaches a swivel connector between an implant device and an internal body conduit (column 7, lines 44-45; column 8, lines 36-42). It would have been obvious to apply the swivel joint taught by Inman et al between the subhousing and the housing of the modified device of Cuppy since the swivel joint can have various bends or angles (column 8, lines 39-42) that allow the subhousing to be moved in a direction that is more comfortable for the patient's body.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cuppy and Inman et al, as applied to claim 3 above, and further in view of Black (US 5,092,854).

In regards to claim 4, Cuppy does not teach a swivel joint that provides a 360 degree range of motion. While Inman et al teaches the application of a swivel connector (column 7, lines

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44-45; column 8, lines 36-42), Inman et al is silent about the range of motion of the swivel joint. However, Black teaches a swivel connector with 360° of motion (column 2, lines 64-68) so that a tip, such as the subhousing, can be oriented in any desired direction (column 1, lines 67-68 to column 2, lines 1-2). It would have been obvious to apply the swivel connector taught by Inman et al and Black between the subhousing and housing of Cuppy so that the subhousing can be moved in any direction, within 360° of motion, that is more comfortable for the patient's body based on complete range of motion.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cuppy and Inman et al, as applied to claim 1 above, and further in view of Ryan (US 5,338,314).

In regards to claim 5, Cuppy does not teach a luer-style connector for securing the housing to the catheter. Ryan teaches that a luer is provided between a Y-connector body and a catheter (column 1, lines 67-68). To a person having ordinary skill in the art, it would have been obvious to apply the luer-style connector taught by Ryan to the modified device of Cuppy because Ryan teaches that a swivel luer-style connector not only swivel connects a catheter to a housing, but it also provides an effective seal between the catheter and the housing (column 3, lines 35-42).

7. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuppy and Inman et al, as applied to claim 19 above, and further in view of Merry et al (US 4,929,235).

In regards to claims 21 and 22, Cuppy does not teach of inserting a wire-based treatment device, such as a guide wire, a balloon catheter, or a pressure sensor, through the self-sealing

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injection port and into the vascular system of the patient. Merry et al teaches that tubes such as balloon catheters can be inserted into the body by way of a self-sealing valve-gasket (column 1, lines 7-17). It would have been obvious to insert such a wire-based treatment device as taught by Merry et al through the modified device of Cuppy since certain medical procedures often require one tube to be inserted into another tube into a vessel with the second tube being sealed at all times (column 1, lines 13-17) to maintain a sterile medical environment.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shefali D. Patel whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDP
09/04/07



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